

(d) *Supplemental statements.* Where substantial changes occur or new information becomes available under a project or activity for which an EIS or draft EIS has been prepared and it is determined by a responsible NIFA official specified in §3407.4(b) that the changes are pertinent to environmental concerns, a supplement to the EIS or draft EIS may be required. The supplement shall be evaluated and processed in accordance with 40 CFR 1502.9(c).

(e) *Decisionmaking and implementation.* A responsible NIFA official designated in §3407.4(b) may make a decision no sooner than thirty days after the notice of availability of the final EIS has been published in the FEDERAL REGISTER by the Environmental Protection Agency (40 CFR 1506.10). The decision will be documented in a record of decision as required by 40 CFR 1505.2, and monitoring and mitigation activities will be implemented as required by 40 CFR 1505.3.

## **PART 3411—NATIONAL RESEARCH INITIATIVE COMPETITION GRANTS PROGRAM [RESERVED]**

## **PART 3415—BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM**

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EDITORIAL NOTE: Nomenclature changes to part 3415 appear at 76 FR 4811, Jan. 27, 2011.

### **Subpart A—General**

#### **§ 3415.1 Applicability of regulations.**

(a) The regulations of this part apply to research grants awarded under the authority of section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990, (7 U.S.C. 5921). Grants awarded under this section will support biotechnology risk assessment research to help address concerns about the effects of introducing certain biotechnology products into the environment and to help regulators develop policies concerning the introduction of such products. Taking into consideration any determinations made through consultations with such entities as the Animal and Plant Health Inspection Service, the Forest Service, the Environmental Protection Agency, the Office of Agricultural Biotechnology, and the Agricultural Biotechnology Research Advisory Committee, the Director of NIFA and Administrator of ARS shall determine and announce, through publication of a Notice in such publications as the FEDERAL REGISTER, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance, or any other appropriate means, specific areas of research for which preproposals or proposals will be solicited and the extent that funds are available therefor.

(b) The regulations of this part do not apply to grants awarded by the Department of Agriculture under any other authority.

#### **§ 3415.2 Definitions.**

As used in this part:

(a) *Ad hoc reviewers* means experts or consultants qualified by training and experience in particular scientific or technical fields to render special expert advice, through written evaluations of grant applications, in accordance with the provisions of this part, on the scientific or technical merit of grant applications in those fields.

(b) *Administrator* means the Administrator of the Agricultural Research

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Service (ARS) and any other officer or employee of the Department of Agriculture to whom the authority involved may be delegated.

(c) *Awarding official* means the Director or Administrator and any other officer or employee of the Department to whom the authority to issue or modify grant instruments has been delegated.

(d) *Biotechnology* means any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included.

(e) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(f) *Department* means the Department of Agriculture.

(g) *Director* means the Director of the National Institute of Food and Agriculture (NIFA) and any other officer or employee of the Department of Agriculture to whom the authority involved may be delegated.

(h) *Grant* means the award by the Director or Administrator of funds to a grantee to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research program area identified in program solicitation.

(i) *Grantee* means the entity designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(j) *Peer review group* means an assembled group of experts or consultants qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications in those fields.

(k) *Principal investigator* means a single individual who is responsible for the scientific and technical direction of the project, as designated by the grantee in the grant application and approved by the Director or Administrator.

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(l) *Project* means the particular activity within the scope of one or more of the research program areas identified in the annual program solicitation that is supported by a grant under this part.

(m) *Project period* means the total time approved by the Director or Administrator for conducting the proposed project as outlined in an approved grant application.

(n) *Research* means any systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(o) *Methodology* means the project approach to be followed to carry out the project.

[58 FR 65647, Dec. 15, 1993, as amended at 76 FR 4811, Jan. 27, 2011]

### § 3415.3 Eligibility requirements.

(a) Except where otherwise prohibited by law, any public or private research or educational institution or organization shall be eligible to apply for and to receive a grant award under this part, provided that the applicant qualifies as a responsible grantee under the criteria set forth in paragraph (b) of this section.

(b) To qualify as responsible, an applicant must meet the following standards as they relate to a particular project:

(1) Adequate financial resources for performance, the necessary experience, organizational and technical qualifications, and facilities, or a firm commitment, arrangement, or ability to obtain same (including by proposed sub-agreements);

(2) Ability to comply with the proposed or required completion schedule for the project;

(3) Satisfactory record of integrity, judgment, and performance, including, in particular, any prior performance under grants or contracts from the Federal government;

(4) Adequate financial management system and audit procedures that provide efficient and effective accountability and control of all funds, property, and other assets; and

(5) Otherwise be qualified and eligible to receive a grant under the applicable laws and regulations.

(c) Any applicant who is determined to be not responsible will be notified in